#### PATENT COOPERATION TREATY

\$chwegman Lundberg & Woessner P.A.

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

AUG 22 2011

To: NOTIFICATION OF TRANSMIREGEIVED Perdok Shonka, M.M. SCHWEGMAN, LUNDBERG & WOESSNER, P.A. THE WRITTEN OPINION OF THE INTERNATIONAL P.O. Box 2938 SEARCHING AUTHORITY, OR THE DECLARATION Minneapolis, MN 55402-0938 **ETATS-UNIS D'AMERIQUE** (PCT Rule 44.1) Date of mailing (day/month/year) 16 August 2011 (16-08-2011) Applicant's or agent's tile reference 3063025WO1 FOR FURTHER ACTION See paragraphs 1 and 4 below International filing date International application No. (day/month/year) PCT/US2010/045375 12 August 2010 (12-08-2010) Applicant BIOVAIL LABORATORIES INTERNATIONAL (BARBADOS...

1.	X	The applicant is hereby notitied that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.  Filling of amendments and statement under Article 19: The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):					
		When?	The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.				
		Where?	Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Fascimile No.: (41-22) 338.82.70				
		For mor	e detailed instructions, see PCT Applicant's Guide, International Phase, paragraphs 9.004 - 9.011.				
2.		The applica	ant is hereby notitied that no international search report will be established and that the declaration under ()(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.				
3.		With regar	d to any protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:				
			otest together with the decision thereon has been transmitted to the International Bureau together with the cant's request to forward the texts of both the protest and the decision thereon to the designated Offices.				
		no de	cision has been made yet on the protest; the applicant will be notified as soon as a decision is made.				

#### 4. Reminders

The applicant may submit comments on an intormal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. Following the expiration of 30 months from the priority date, these comments will also be made available to the public.

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. It the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before completion of the technical preparations for international publication (Rules 90*bis.*1 and 90*bis.*3).

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be tiled if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time\_limits.html and the *PCT Applicant's Guide*, National Chapters.

Name and mailing address of the International Searching Authority

European Patent Office, P.B. 5318 Patentlaan 2

NL-2280 HV Rijswijk Tel. (+31-70) 340-2040 Fax: (+31-70) 340-3016 Authorized otticer

WACH, Patrick

Tel: +31 (0)70 340-3325

## PATENT COOPERATION TREATY

# **PCT**

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER		see Form PCT/ISA/220									
3063025W01	ACTION as		well as, where applicable, item 5 below.									
International application No.	International filing date (day/month	/year)	(Earliest) Priority Date (day/month/year)									
PCT/US2010/045375	12/08/2010		12/08/2009									
Applicant												
BIOVAIL LABORATORIES INTERNATIONAL (BARBADOS												
This international search report has been according to Article 18. A copy is being tra			ority and is transmitted to the applicant									
This International search report consists of												
X It is also accompanied by	a copy of each prior art document ci	ted in this	report.									
1. Basis of the report												
a. With regard to the language, the												
<b>=</b>	application in the language in which it	t was filed										
a translation of the of a translation full	e international application into rnished for the purposes of internation	nal search	, which is the language h (Rules 12.3(a) and 23.1(b))									
b. This international search r		ito accoun	nt the rectification of an obvious mistake									
c. With regard to any nucleo	otide and/or amino acid sequence	disclosed	in the international application, see Box No. I.									
2. Certain claims were four	Certain claims were found unsearchable (See Box No. II)											
3. Unity of invention is lack	king (see Box No III)											
4. With regard to the title,												
the text is approved as su	bmitted by the applicant											
	shed by this Authority to read as folio	ws:										
PHARMACEUTICAL COMPOSI	· ·											
5. With regard to the abstract,												
X the text is approved as su	• ''	•										
the text has been establis may, within one month fro	shed, according to Rule 38.2(b), by to om the date of mailing of this interna-	nis Author tional sear	ity as it appears in Box No. IV. The applicant rch report, submit comments to this Authority									
6. With regard to the drawings,												
a. the figure of the <b>drawings</b> to be p	oublished with the abstract is Figure	No7										
X as suggested by												
<u> </u>	is Authority, because the applicant fa											
as selected by the	is Authority, because this figure bett	er charact	erizes the invention									
b. none of the figures is to b	pe published with the abstract											

#### **INTERNATIONAL SEARCH REPORT**

Internattonal application No PCT/US2010/045375

A. CLASSIFICATION OF SUBJECT MATTER INV. A61K9/16 A61K9 A61K9/20 A61K9/28 A61K9/50 A61K31/4375 A61P25/14 ADD. According to International Patent Classification (IPC) or to both national classification and tPC **B. FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) A61K Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, CHEM ABS Data, WPI Data, EMBASE C. DOCUMENTS CONSIDERED TO BE RELEVANT Category\* Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. X WO 2007/007105 A1 (CAMBRIDGE LAB IRELAND 1 - 67LTD [IE]; TRIDGETT ROBERT [GB]; FILLOUX THIERRY) 18 January 2007 (2007-01-18) the whole document WO 2006/069030 A1 (COLLEGIUM Α 1-67 PHARMACEUTICAL INC [US]; RARIY ROMAN V [US]: HEFFERNAN MICHA) 29 June 2006 (2006-06-29) the whole document Α WO 2008/079404 A2 (SPHERICS INC [US]; 1-67 NANGIA AVINASH [US]; JACOB JULES [US]; YEH JAMES [U) 3 July 2008 (2008-07-03) the whole document -/--Χ Further documents are listed in the continuation of Box C. See patent family annex. Special categories of cited documents: "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another involve an Inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention citation or other special reason (as specified) cannot be considered to involve an inventive step when the document referring to an oral disclosure, use, exhibition or document is combined with one or more other such docu ments, such combination being obvious to a person skilled other means document published prior to the international filing date but later than the priorily date claimed "&" document member of the same patent family Date of mailing of the international search report Date of the actual completion of the international search 16/08/2011 5 August 2011 Name and mailing address of the ISA/ Authorized officer European Patent Office, P.B. 5818 Patentiaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Glikman, J Fax: (+31-70) 340-3016

1

## **INTERNATIONAL SEARCH REPORT**

International application No PCT/US2010/045375

Catogory*	Citation of document with indication, where apprendicts of the relevant recessor	Relevant to claim No.
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	WO 2010/018408 A2 (BIOVAIL LAB INTERNAT BARBADOS [BB]; DUFFIELD ANDREW JOHN [GB]; JACKSON) 18 February 2010 (2010-02-18) the whole document	1-6/

1

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2010/045375

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2007007105 A1	18-01-2007	AT 409481 T AU 2006268098 AI CA 2615077 AI CN 101282726 A DK 1885363 TI EP 1885363 AI EP 2027861 A ES 2314931 TI HK 1111085 A HR 20080677 T JP 2009501202 A KR 20080030666 A NZ 565522 A	1 18-01-2007 08-10-2008 3 08-12-2008 1 13-02-2008 1 25-02-2009 3 16-03-2009 1 05-06-2009
		PT 1885363 E SI 1885363 T US 2008319000 A ZA 200800905 A	08-01-2009 1 28-02-2009
WO 2006069030 A1	29-06-2006	AU 2005319367 A CA 2590802 A CN 101132777 A EP 1833467 A JP 2008524332 A KR 20070087678 A US 2008200508 A	1 29-06-2006 27-02-2008 1 19-09-2007 10-07-2008 28-08-2007
WO 2008079404 A2	2 03-07-2008	AU 2007338631 A CA 2673511 A EP 2063867 A US 2010316712 A	1 03-07-2008 2 03-06-2009
WO 2010018408 A2	2 18-02-2010	GB 2462611 A US 2010055133 A	